Remarks

Claims 49 and 50 were pending in this application. Claim 49 is amended as suggested by the Examiner. Support for this amendment can be found throughout the specification, for example at page 6, lines 25-29 and in original claim 49.

No new matter is introduced by the foregoing amendments. After entry of this Amendment, **claims 49 and 50 are pending in this application**. Consideration and allowance of the pending claims is requested.

Claim Objection

Claims 49 and 50 are objected to for several informalities. Applicants thank Examiner Marvich for suggesting amendments to claim 49 to remedy the highlighted deficiencies. Claim 49 has been amended as suggested by the Examiner.

Applicants respectively request withdrawal of the objection to claims 49 and 50.

Rejection under 35 U.S.C. §102(b)

Claims 49 and 50 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Allen *et al.* on the grounds that Allen *et al.* teaches "a vector comprising an HIV-2 packaging signal and a heterologous nucleic acid and sequences encoding an SIV envelope" (Office action, at page 3). Applicants traverse this rejection.

Applicants submit that the vectors of Allen *et al.* do not fall within the scope of the present claims, and the rejection is, at least in part, based on the erroneous assumption that the SIV env protein is the same as the SIV capsid. In fact, for the reasons set out below, there is no disclosure whatsoever in Allen *et al.* of chimaeric viruses as presently claimed.

Allen *et al.* relates to vectors based on HIV-2. In all of the virions disclosed in Allen *et al.*, the core structural proteins are HIV-2 in origin. In particular, the gag protein (which is later cleaved to form the capsid, matrix, and nucleocapsid proteins) is derived entirely from HIV-2. The HIV-2 gag protein recognizes HIV-2 nucleic acids containing the HIV-2 RNA packaging

signal. The RNA plus the gag protein and its derivatives form the core of the vector or virus particle.

Allen *et al.* discloses the use of the SIV env protein in paragraph [0059], which states:

> *These attenuated virions are extremely useful in preparing a vaccine. The virions can be used to generate an antibody response to HIV-2 virions and, because these virions are identical to the actual HIV-2 virions except that the interior of these virions do not contain the viral RNA, the vaccine created should be particularly useful. Pseudotyped virions produced from cell lines cotransfected with HIV-2 gag/pol and protease genes and containing the env gene from another virus may be useful in creating a vaccine against this other virus. For example, an SIV env vector in the cell may give rise to a viral particle with an SIV env capable of eliciting an antibody response to SIV but without pathogenicity because of the absence of any other SIV proteins or SIV RNA.*

In other words, according to Allen *et al.,* in the layer surrounding the viral core, *i.e.* the envelope layer, one may insert heterologous proteins from other viruses, including the SIV envelope protein. This would have the effect of targeting the particle to a different cell type and eliciting a different immune response. However, this optional SIV envelope protein does not have any function in the recognition of the HIV-2 RNA by the HIV-2 gag protein.

Furthermore, Allen *et al.* specifically state that no other SIV proteins or RNA are present in the pseudotyped virions. Since the only SIV protein present in the pseudotyped virions is an optional external envelope protein, there is no disclosure in Allen *et al.* of any SIV proteins which are directly involved in forming the intact core of the vector particle. Allen *et al.* is totally silent about the possibility of using the SIV gag protein to recognize and capture the nucleic acid that goes into the centre of the particle. The virions of Allen *et al.* therefore lack "*Simian Immunodeficiency Virus (SIV) nucleic acid sequences encoding an SIV capsid*" as required by the present claims.

Additionally, paragraph [0059] of Allen *et al.* relates to "*attenuated virions*". These virions "*do not contain the viral RNA*" and are therefore useful as vaccines. There is no suggestion in Allen *et al.* that the SIV envelope protein might be used in any other context. By

contrast the present claims require that the chimaeric virus comprises "*heterologous nucleic acid sequence encoding the therapeutic or the antigenic protein or peptide*".

In summary, there is no disclosure or suggestion in Allen *et al.* of chimaeric viral vectors that comprise heterologous nucleic acid linked to HIV-2 packaging signals contained within an SIV viral capsid as set out in the instant claims. Claims 49 and 50 are therefore not anticipated by Allen *et al.* Applicants request withdrawal of this rejection of claims 49 and 50.

Conclusion

Based on the foregoing amendments and arguments, the pending claims are in condition for allowance, and notification to that effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the telephone number listed below.

Respectfully submitted,

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